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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,096	09/18/2003	Brian R. MacDonald	PRD-2110-USANP	1638

27777 7590 04/07/2009  
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ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
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BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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04/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/667,096	<b>Applicant(s)</b> MACDONALD ET AL.	
	<b>Examiner</b> Bridget E. Bunner	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-12, 15-19 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12, 15-19, 26-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 and 01 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 08 January 2009 has been entered in full. Claims 2 and 9-12 are amended. Claims 1, 13, 14, 20-25 are cancelled.

Claims 2-12, 15-19, and 26-34 are under consideration in the instant application.

### ***Withdrawn Objections and/or Rejections***

1. The rejection of claim 34 under 35 U.S.C. §112, first paragraph (written description, new matter) as set forth at pages 4-5 of the previous Office Action (08 October 2008) is *withdrawn* in view of Applicant's persuasive arguments (08 January 2009).

### ***New Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-12, 15-19, and 26-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

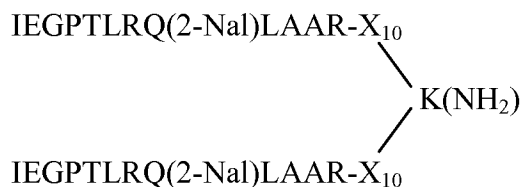
2a. Claims 2-12, 15-19, and 26-34 recite the limitation "X<sub>10</sub> is Sar" in the last line of claims 2 and 9-12. There is insufficient antecedent basis for this limitation in the claims.

### ***Maintained Objections/Rejections***

**35 U.S.C. 132**

3. The amendment filed 22 May 2006 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. Applicant has introduced new matter at page 7 in the specification. Specifically, the amended description at page 7, between lines 9-10 indicates that a preferred TPO mimetic compound is IEGPTLRQ(2-Nal)LAARX<sub>10</sub> where X<sub>10</sub> is a sarcosine or  $\beta$ -alanine residue or pegylated form of this compound. However, page 7, lines 8-9 in the original specification of 9/18/03 only recite a preferred TPO mimetic of IEGPTLRQ(2-Nal)LAARA (emphasis added by the Examiner). The original specification does not teach a TPO mimetic monomer missing an alanine at the end of the sequence. The original specification also does not teach a monomer with an X<sub>10</sub> group attached, where X<sub>10</sub> represents a sarcosine or  $\beta$ -alanine residue or pegylated form of the compound.

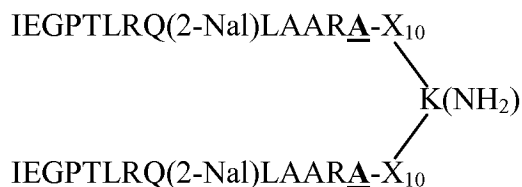
Furthermore, Applicant has introduced new matter at page 7, between lines 20-21 in the specification. The amended description indicates another preferred TPO mimetic compound with the following formula:



wherein X<sub>10</sub> is a sarcosine or  $\beta$ -alanine residue or a pegylated form of the compound.

However, page 7, lines 13-18 in the original specification of 9/18/03 only recite a preferred TPO mimetic of

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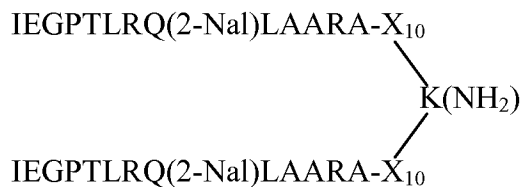
wherein X<sub>10</sub> is a sarcosine or β-alanine residue or a pegylated form of the compound (emphasis added by the Examiner). The original specification does not teach a TPO dimer or oligomer missing an alanine between the arginine and X<sub>10</sub> at the end of the sequence.

Applicant is required to cancel the new matter in the reply to this Office Action. The basis for this objection is set forth at pages 2-3 of the previous Office Action (08 October 2008).

Applicant's arguments (08 January 2009), as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

At the top of page 7 of the Response, Applicant argues that a peptide as described in corresponding application 60/498,740 (attorney docket number 038073-5005PR) could be employed in accordance with the method of the invention. Applicant refers the Examiner to page 6, lines 8-9 of 60/498,740. Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, at page 6, lines 1-9, the specification of '740 teaches:

"...the peptide compounds of the present invention are preferably dimerized or oligomerized to increase the affinity and/or activity of the compounds. An example of a preferred dimerized peptide compound includes, but is not limited to, the following:



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Where  $X_{10}$  is a sarcosine or  $\beta$ -alanine residue. The above structure can also be represented by the following structure:  $(H-IEGPTLRQ(2-Nal)LAARX_{10})_2K-NH_2$ ."

Page 6, lines 5-7 of the '740 application discloses the same dimer as originally disclosed in the specification of the instant application. It appears that the "shorthand" structure at page 6, lines 8-9 of the '740 application  $((H-IEGPTLRQ(2-Nal)LAARX_{10})_2K-NH_2)$  is a typo since the alanine between the arginine and  $X_{10}$  at the end of the sequence is missing. The alanine is clearly present in the dimerized peptide compound that is written out "longhand".

It is also noted that Applicant has not addressed the new matter introduced at page 7, lines 9-10 in the specification. The '740 application does not provide support for a preferred TPO mimetic compound,  $IEGPTLRQ(2-Nal)LAARX_{10}$  where  $X_{10}$  is a sarcosine or  $\beta$ -alanine residue or pegylated form of this compound. The original specification does not teach a TPO mimetic monomer missing an alanine at the end of the sequence.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

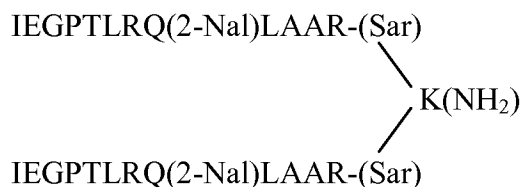
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2-12, 15-19, and 26-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

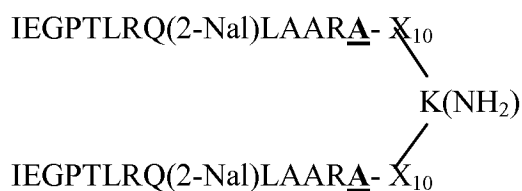
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claimed invention. This is a new matter rejection. The basis for this rejection is set forth at pages 5-6 of the previous Office Action (08 October 2008).

The specification as originally filed does not provide adequate written description for a TPO mimetic having the following formula:



This compound is not expressly asserted, nor does it flow naturally from the specification. The originally filed specification of 18 September 2003 only discloses that “a particularly preferred TPO mimetic peptide is IEGPTLRQ(2-Nal)LAARAA” (page 7, lines 8-9; emphasis added by the Examiner). The originally filed specification also discloses that the mimetic compound is dimerized or oligomerized and an example includes (emphasis added by the Examiner):



wherein X<sub>10</sub> is a sarcosine or β-alanine residue or a pegylated form of the compound.

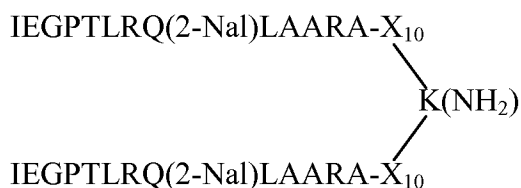
Thus, the original specification does not teach a dimer or oligomer without an alanine after an arginine at the end of the sequence.

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Applicant's arguments (08 January 2009), as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

At the bottom of page 7 of the Response, Applicant argues that a peptide as described in corresponding application 60/498,740 (attorney docket number 038073-5005PR) could be employed in accordance with the method of the invention. Applicant refers the Examiner to page 6, lines 8-9 of 60/498,740. Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, at page 6, lines 1-9, the specification of '740 teaches:

"...the peptide compounds of the present invention are preferably dimerized or oligomerized to increase the affinity and/or activity of the compounds. An example of a preferred dimerized peptide compound includes, but is not limited to, the following:



Where  $X_{10}$  is a sarcosine or  $\beta$ -alanine residue. The above structure can also be represented by the following structure: (H-IEGPTLRQ(2-Nal)LAARX<sub>10</sub>)<sub>2</sub>K-NH<sub>2</sub>."

Page 6, lines 5-7 of the '740 application discloses the same dimer as originally disclosed in the specification of the instant application. It appears that the "shorthand" structure at page 6, lines 8-9 of the '740 application ((H-IEGPTLRQ(2-Nal)LAARX<sub>10</sub>)<sub>2</sub>K-NH<sub>2</sub>) is a typo since the alanine between the arginine and X<sub>10</sub> at the end of the sequence is missing. The alanine is clearly present in the dimerized peptide compound that is written out "longhand".



***Conclusion***

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB  
Art Unit 1647  
30 March 2009

/Bridget E Bunner/  
Primary Examiner, Art Unit 1647